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Conceptualizing the landscape of digital health entrepreneurship: a systematic review and research agenda

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Abstract

Digital health, which encompasses the use of digital technology to enhance and support healthcare, can potentially transform the healthcare industry. As healthcare systems struggle to provide high-quality care, entrepreneurs and startups have turned to digital health technology to create innovative products and services that aim at improving healthcare outcomes and reducing costs. This has made digital health entrepreneurship a major driving force for achieving good health and high-quality care. The study aims to analyze the current state of research in digital health entrepreneurship by identifying contributing disciplines and common research themes. A comprehensive literature review based on state-of-the-art definitions of digital health entrepreneurship was conducted to achieve this goal. A total of 164 articles met the final inclusion criteria, and the subsequent inductive analysis revealed the presence of three contributing disciplines and ten distinct themes: Academia Transfer and Education, Ecosystem and Stakeholder, Product and Business Development, Business Model, Classification, Management and Strategy, Regulation, Digital Technology, Implementation and Adoption, and Evaluation. These themes were organized into a conceptual framework depicting the internal and external building blocks of digital health entrepreneurship. The review highlights the importance of a structured understanding of the industry, including its business models and regulatory environment, as well as the role of the various healthcare stakeholders. This analysis can guide researchers and entrepreneurs seeking to navigate the digital health landscape and proposes further research avenues.

Keywords Digital health · Telehealth · eHealth · Startup · Entrepreneurship · Innovation

JEL Classification I100 · K230 · M130

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1 Introduction and motivation

Worldwide healthcare systems face significant challenges, including rising healthcare costs (Wulfovich 2020), outcome problems (Herrmann et al. 2018), and aging populations with a high prevalence of multimorbidities (Bratan et al. 2022). To face these challenges, innovative healthcare solutions are a key social and economic priority (Bratan et al. 2022) and are crucial for achieving high-quality healthcare (Friebe 2020). Accordingly, the United Nations has defined good health and well-being as one of the sustainable development goals (SDGs) (Bratan et al. 2022). Responding to these issues, healthcare systems are increasingly adopting precision medicine, disease prevention, and value-based healthcare, in which providers are rewarded for long-term health outcomes and the well-being of their patients (Friebe 2020).

Digitalization has significantly impacted various industries, resulting in the emergence of previously unimaginable products and services (Sreenivasan and Suresh 2022). Several digital technologies drive this transformation, including computers, the internet, smartphones, and vast amounts of data. The healthcare industry has particularly felt the effects of digitalization with the adoption of health apps, virtual doctor appointments, and more (Denoo and Yli-Renko 2019). Furthermore, the recent COVID-19 pandemic has accelerated digitalization (Golinelli et al. 2020). Digital solutions have the potential to address the challenges mentioned above, empower patients, and improve access to care in rural communities (Wulfovich 2020; Tariq 2023). However, some hurdles prevent the success of digital health solutions (Ahmed et al. 2019). These include regulatory barriers in the healthcare sector, which are in place to ensure the safety and quality of medical products (Herrmann et al. 2018). Additionally, user acceptance has been low but is crucial, especially when collecting sensitive health data (Wilkowska and Ziefle 2012).

The convergence of the need for innovation in healthcare and the potential offered by digitalization, together with other factors such as the COVID-19 pandemic, has given rise to the field of digital health entrepreneurship. It studies how digital health ventures pursue opportunities to deploy digital healthcare innovations in uncertain conditions (Wulfovich 2020).

1.1 Digital health and entrepreneurship evolution

To understand the current state of digital health entrepreneurship and related challenges, it is helpful to primarily examine the evolution of the terms digital health and entrepreneurship.

Digital health encompasses a range of concepts and technologies, including electronic health (eHealth), mobile health (mHealth), wearable devices, telehealth, telemedicine, health information technology, and artificial intelligence (WHO 2019; FDA 2022).

Over the past few decades, digital health terminology has evolved significantly, with many terms overlapping in meaning. However, the core goal of digital health remains the same: to use digital technology to improve patient care.

In the 1970s, medical informatics and telemedicine were coined (Kazley et al. 2012; Chen et al. 2020). In the following decades, information and communication technology (ICT) for health and telehealth emerged, shifting the focus from disease-specific medicine to broader health issues. After 2000, eHealth and mHealth were established (Chen et al. 2020), with mHealth often defined as a subcategory of eHealth (Otto et al. 2020; Alenoghena et al. 2022). Although each term emerged based on the needs of its time, they often overlap and cannot always be distinguished. With the growing impact of digitalization in healthcare, the term digital health has emerged as an umbrella term encompassing a variety of related concepts (WHO 2019; FDA 2022). This development is illustrated in Fig. 1, and an overview of the terms and their definitions are provided in Table 1. These terms are predominantly utilized in the context of digital health.

While digital health represents the broad concept of integrating digital technologies into healthcare and wellness, the term digital health technology (DHT) has emerged to specifically denote the digital technologies that are employed to achieve this integration. As of now, there is no international harmonized DHT framework. According to ISO (2023), DHT encompasses systems that use computing platforms, connectivity, software, and sensors for healthcare and related uses. Although some DHTs are part of the medical technology (MedTech) product family, have a medical purpose and thus are regulated as medical devices, others do not fall under the regulatory umbrella of medical devices. This is illustrated in Fig. 2. The subset of DHT that is regulated is known as Software as a Medical Device (SaMD). SaMD is a subcategory of DHT and refers to software that is intended to be used for one or more medical purposes that are performed without being part of a hardware medical device (IMDRF 2014).

A subcategory of SaMD are Digital Therapeutics (DTx) (Fürstenau et al. 2023). A DTx product refers to software intended to treat or alleviate a disease, disorder, condition, or injury by generating and delivering a medical intervention that has a demonstrable positive therapeutic impact on a patient's health (ISO 2023). Besides

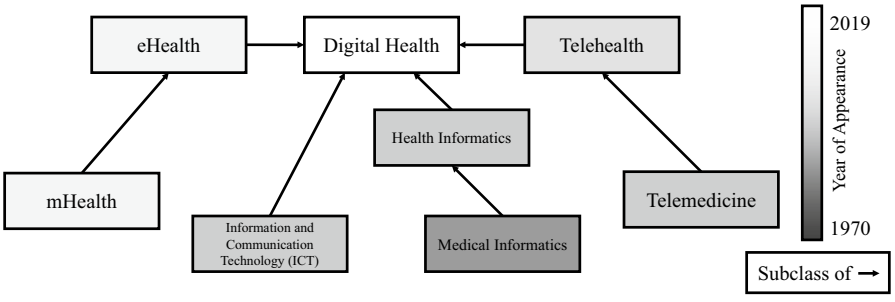

Fig. 1 The affiliation between the most important terminology used in the context of digital health according to year of appearance

Table 1 A summary of the terminology used to describe the field of digital health

Term	Description
Digital Health	Digital Health is a broad umbrella term encompassing electronic health (eHealth), mobile health (mHealth), wearable devices, telehealth, telemedicine, health information technology, and artificial intelligence applied in healthcare (WHO 2019; FDA 2022)
Medical and health informatics	Both terms encompass collecting, analyzing, and transmitting health data and information to support health care (Chen et al. 2020)
ICT for health	Information and communication technology (ICT) for health fulfills or enables information processing and communication by electronic means (Otto et al. 2020)
Telemedicine and telehealth	Both terms use ICT over distances to deliver healthcare services and medical education. Telemedicine focuses on service delivery through physicians, while telehealth includes all healthcare providers (Chen et al. 2020; Otto et al. 2020)
eHealth	Electronic Health (eHealth) refers to tools and services using information and communication technologies to improve prevention, diagnosis, treatment, monitoring and management (Otto et al. 2020)
mHealth	Mobile Health (mHealth) is the use of mobile communication for health information and services and is often defined as a subclass of eHealth (Alenoghena et al. 2022)

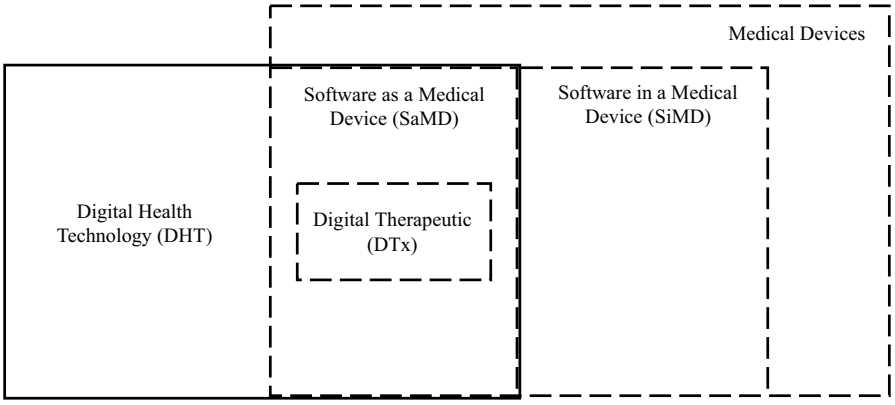

Fig. 2 Digital Health Technology (DHT) and the related terminology in the context of medical devices, adapted from ISO (2023)

standalone applications, digital approaches are often also used in hardware medical devices (Gilbert et al. 2023). If the software is not standalone and serves as an integral component of a specified hardware medical device or is intended to drive a hardware medical device, it is referred to as Software in a Medical Device (SiMD). As shown in Fig. 2, SiMD is not part of DHT (ISO 2023).

Despite the fact that numerous definitions of entrepreneurship exist, it has often been framed as examining how, by whom, and with what effects opportunities to create future goods and services are discovered, evaluated, and exploited (Shane and

Venkataraman 2000). Entrepreneurs exploit opportunities such as new technologies with different levels of innovation (Christensen 1997). Innovation is seen as the driving force for the entrepreneurial process (Drucker 1985). The transformative impact of digital technologies has greatly influenced the evolution of entrepreneurship. These advancements have given rise to many new business opportunities while fundamentally reshaping the nature of entrepreneurship (Denoo and Yli-Renko 2019). In this scope, digital entrepreneurship has been defined as creating new ventures by developing or using such digital technologies (Baierl et al. 2019).

Building on these insights and the definitions of Wulfovich (2020), Shane and Venkataraman (2000), and Baierl et al. (2019), digital health entrepreneurship can be defined as a field that examines the pursuit of deploying digital health innovations by leveraging digital technologies to benefit patients or the wider health and social care system.

1.2 Research questions

The field of digital health entrepreneurship is rapidly evolving, and further research is needed to fully understand its potential and challenges (Denoo and Yli-Renko 2019; Sreenivasan and Suresh 2022).

To fill the gap of a structured understanding of the field in the literature, this work aims to comprehensively review digital health from an entrepreneurial perspective. The primary objective is to map the scientific evidence and to identify areas that necessitate further research. Accordingly, three research questions (RQs) are formulated to achieve this goal:

- *RQ1* Which disciplines contribute to the field of digital health entrepreneurship and which research methodologies are employed?
- *RQ2* What are the key thematic clusters within the field of digital health entrepreneurship?
- *RQ3* Which research gaps and fruitful directions can be identified?

By identifying research opportunities, the goal is to contribute to developing a more robust evidence base in this critical area and support the ongoing growth and development of the digital health sector.

The remainder of this work is structured as follows: The next section describes the scientific methods employed to investigate the research questions. Next, the findings from the literature review are presented through a citation network and a conceptual framework. The subsequent discussion section provides a detailed exploration of the results obtained from the literature. Finally, the work concludes with a summary of the essential findings and their implications.

2 Methodology

We conducted a systematic literature review according to Kraus et al. (2020) and vom Brocke et al. (2009). A systematic literature review is a rigorous research method that creates findings in a reproducible manner and, thus, helps to create an unbiased synthesis (Kraus et al. 2020). Additionally, it is a suitable method to explore research gaps fitting to the research scope of this work (Brocke et al. 2009). Kraus et al. (2020) define four steps of a systematic literature review which were followed in this work: Planning the review, identifying and evaluating studies, extracting and synthesizing data, and disseminating the review findings.

2.1 Planning the review

Following a preliminary examination of the literature by searching for 'digital health entrepreneurship' on Scopus, we have precisely delineated the research questions that will serve as the foundation for guiding the review planning process. The questions were formulated in response to the research gaps identified during the primary investigations. As an additional step of the review planning process, we decided to conduct the subsequent search on three databases to include most articles: Web of Science, Scopus, and PubMed. PubMed was selected to find relevant medical literature, whereas Web of Science and Scopus index relevant entrepreneurship literature as the central databases (Kraus et al. 2020).

2.2 Identification of literature

The subsequent phase of the systematic literature review involved the identification of relevant search terms. Synonyms and related terms were added to the two core concepts of digital health and entrepreneurship based on the terminology used in the field. Table 2 lists the final keywords and their associated terms. A composed search string was created based on the keywords, combining the core concepts with the connector 'AND' and the respective synonyms with 'OR'. Finally, the composed search query was applied to the search engines chosen as part of the planning. The search was limited to the title, abstract, and keywords of the publications. After removing duplicates, a total of 6993 articles remained.

Table 2 The core concepts and related keywords making up the search query, with an asterisk denoting the inclusion of multiple word endings

Core concept	Related search terms
Digital health	digital health*, mobile health, mhealth*, m-health*, ehealth*, e-health*, telemedicine, tele-medicine*, telehealth*, tele-health*, software as a medical device*, digital therapeutic*, healthtech*, health-tech*, medtech*, med-tech*
Entrepreneurship	entrepreneur*, startup*, new venture, new firm, new business, innovation*

Table 3 The inclusion and exclusion criteria that were applied throughout the search process

Inclusion criteria	Exclusion criteria
• English and German language • Peer-reviewed articles • Connection to entrepreneurship research • Relevant in the scope of modern digital technology	• Not enough theoretical contributions • Business and entrepreneurial aspects play only a minor role • No significant connection to digital health • No access to the full paper

2.3 Study selection strategy

Title and abstracts were scanned according to the inclusion and exclusion criteria summarized in Table 3. These criteria were thoughtfully chosen to maximize the outcomes. The search was limited to peer-reviewed publications to focus on high-quality work and adequately answer the research question. Additionally, entrepreneurship and business aspects should be significant in the papers. Due to the rapid evolution of digital technology, only literature with clear connections to modern digital technology was included. The full text was analyzed for the remaining 499 papers, and the inclusion and exclusion criteria were further applied. The ranking of the journal in which the paper was published and the number of citations it received were used as quality indicators to guide the selection, resulting in 141 articles.

From the 141 publications included, 16 additional papers were found through a forward and backward search. As a result of some research articles appearing in monographs, an additional seven items were added based on a manual hand search. The literature selection resulted in the identification of 164 publications, which were included in the final dataset. The entire review and selection process is visualized in Fig. 3.

2.4 Extracting and synthesizing data

Based on the selected literature, themes were derived according to Braun and Clarke (2006). Themes are described as patterned responses within the dataset. Thematic analysis is a foundational method for qualitative analysis with benefits such as flexibility compared to other qualitative methods (Braun and Clarke 2006). Prominent features of textual data were coded and then collated into themes. In an ongoing analysis, the specifics of each theme were redefined to generate clear definitions and names for each theme. In addition, themes were discussed within the research team. Final themes were mapped into a concept matrix, as Webster and Watson (2002) and Brocke et al. (2009) proposed.

3 Results

The connection of the publications to entrepreneurship and startup research varies, and not all papers explicitly mention entrepreneurship, new ventures, or startups. The papers do, however, all relate to some extent to pursuing opportunities to deploy

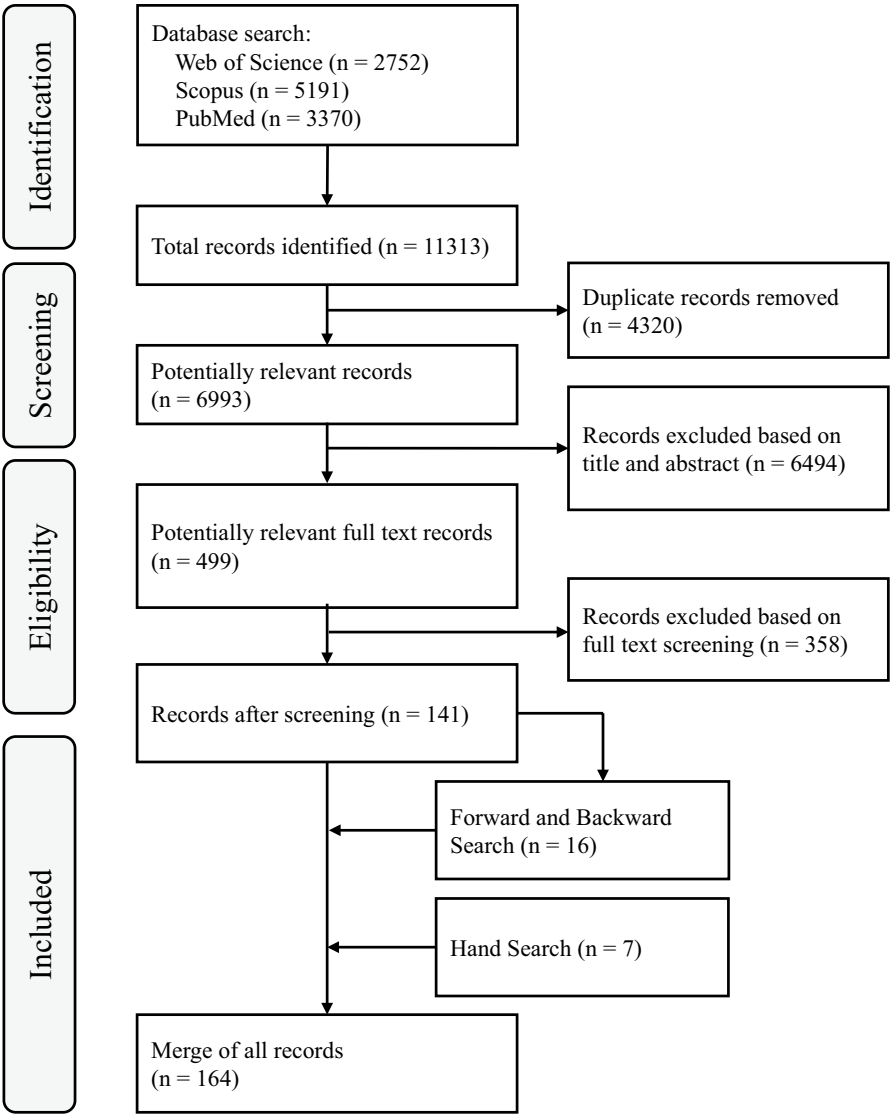

Fig. 3 An overview of the literature search and selection strategy

digital health innovations and are, therefore, relevant to entrepreneurship in digital health.

Figure 4 illustrates the increasing trend in the number of digital health entrepreneurship publications over the years, indicating a growing research interest. Despite an unrestricted search period, the earliest paper identified was published in 2006. By applying the inclusion and exclusion criteria, papers published before 2006 were

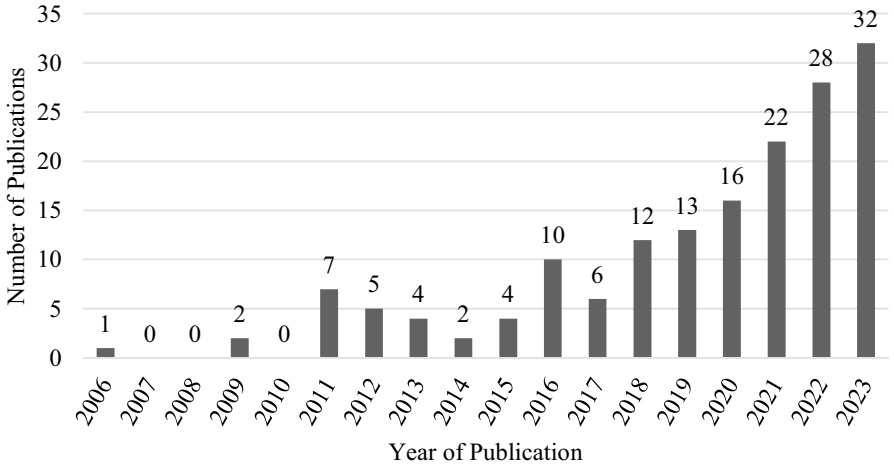

Fig. 4 The number of publications in the dataset per year up to 2023

removed since they did not reflect modern digital technology or the challenges that digital health entrepreneurs face today.

Through a thorough analysis of journals, we sought to gain a deeper understanding of research outlets and the publications they host. The largest number of journals in which digital health entrepreneurship literature is published comes from the field of health and medicine (35%), followed by journals with an explicit focus on digital health (32%). In third place, business journals hold 19% of the publications, followed by engineering journals in fourth place, accounting for 9% of the total publications. Figure 5a summarizes the findings. These disciplines primarily drive digital health entrepreneurship. The 'Journal of Medical Internet Research' led in the number of publications for the dataset, followed by the 'Federal Health Bulletin'. Table 6 in the appendix provides a complete list of the journals ranked according to the number of papers published. In addition to exploring various research

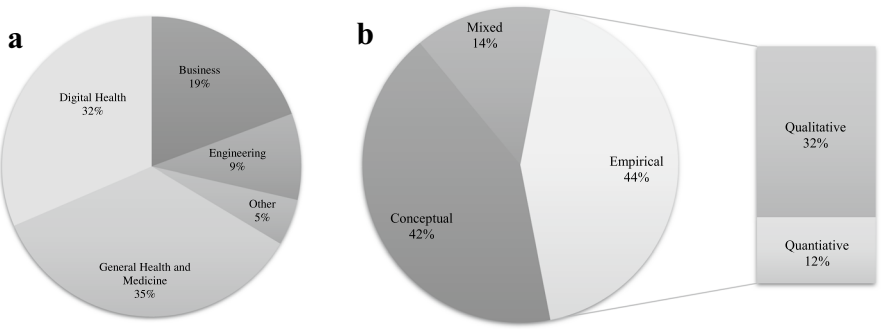

Fig. 5 The percentage of publications belonging to different journal disciplines a and the type of research methodology b

outlets, we analyzed the research methodologies employed in the field by classifying the publications into three distinct methodological clusters: conceptual, empirical, and mixed methods research. As depicted in Fig. 5b, conceptual and empirical approaches comprise 42% and 44% of the total publications. However, mixed methods were utilized in 14% of the studies. Upon closer examination, it became evident that empirical work leaned heavily towards qualitative research methods, constituting 32% of the entire dataset, while quantitative methods were employed by only 12% of the scholars. McDonald et al. (2015) found that quantitative methods predominantly characterize the general entrepreneurship literature. However, a striking contrast emerges in the digital health entrepreneurship literature, where qualitative methods take center stage, overshadowing the relatively limited utilization of quantitative approaches. Concerning potential shifts in research outlets and methods over time, it is worth noting that there have been few significant changes, except for the noticeable increase in publications presented earlier. Generally, research outlets and methods have remained consistent with the increasing number of publications throughout the years.

The programming language R and the visualization tool Gephi were used to construct a citation network including all articles. The network, illustrated in Fig. 6, displays connections between publications and the respective authors. The node size in the network represents the number of connections a publication has to other work. The network primarily comprises one large dominant cluster, surrounded by a few satellite clusters. The most highly-connected works within the network focus on the challenges of scaling up DHT (Greenhalgh et al. 2017), a roadmap to develop digital health products (van Gemert-Pijnen et al. 2011), and a review of digital startups in healthcare (Chakraborty et al. 2021).

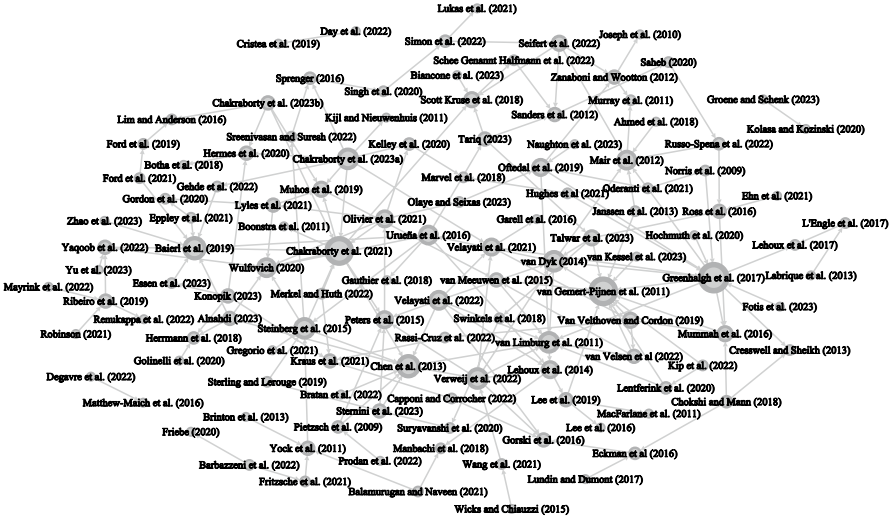

Fig. 6 The citation network for the resulting literature on digital health entrepreneurship with one central cluster and several smaller satellite clusters

A total of ten digital health entrepreneurship themes have emerged from the literature. The themes are Academia Transfer and Education, Ecosystem and Stakeholder, Product and Business Development, Business Model, Classification, Management and Strategy, Regulation, Digital Technology, Implementation and Adoption, and Evaluation. Some publications contribute to multiple themes.

The scope of the ten themes (T) that were identified through the literature review is outlined in the following. The percentage of papers associated with the themes is summarized in Fig. 7. The theme Implementation and Adoption contains the most publications. In contrast, the theme Classification includes the fewest items. Table 5 in the appendix shows a complete list of all publications and their respective theme in the form of a concept matrix.

3.1 Academia transfer and education (T1):

The literature on the Academia Transfer and Education theme focuses on the role of research transfer in universities and teaching digital health entrepreneurial competencies. The articles within this theme discuss topics such as the need for entrepreneurship education in medical curricula and engineering degrees, as well as how to translate promising research into spinoff ventures. (17 publications, 8%).

3.2 Ecosystem and stakeholder (T2)

In the Ecosystem and Stakeholders theme, the involvement of digital health startups with stakeholders is discussed. Additionally, this theme includes articles about the ecosystem of digital health startups, including innovation hubs and living labs, which are integral components. (26 publications, 12%).

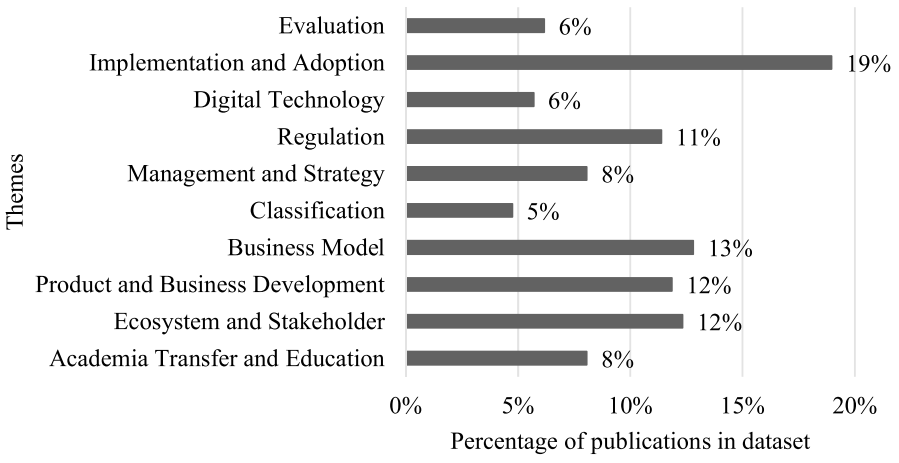

Fig. 7 The percentages of publications belonging to each identified digital health entrepreneurship theme

3.3 Product and business development (T3)

Digital health product design involves utilizing various methods and tools, from human-centered approaches to startup-specific tools. This category addresses entrepreneurial product and business development, focusing on the digital health field. (25 publications, 12%).

3.4 Business model (T4)

The theme of digital health business models discusses the specifics of healthcare business models. Papers within this scope review and theorize around the current business model landscape. (27 publications, 13%).

3.5 Classification (T5)

This theme concentrates on articles that intend to systematically classify and identify patterns within digital health ventures. (10 publications, 5%).

3.6 Management and Strategy (T6)

Management decisions and the strategies employed by digital health entrepreneurs play a significant role in this theme. (17 publications, 8%).

3.7 Regulation (T7)

A complex regulatory landscape surrounds digital health companies. The research included here discusses tools and strategies to facilitate regulatory compliance and overcome these challenges. In this context, the data security and privacy of digital health products are crucial considerations for digital health companies. (24 publications, 11%).

3.8 Digital technology (T8)

Adopting new digital technologies, such as artificial intelligence, blockchain, and wearables, is an essential topic in digital health entrepreneurship. This theme explores the business perspective on adopting these technologies in the digital health industry. (12 publications, 6%).

3.9 Implementation and adoption (T9)

The digital health entrepreneurship literature addresses the implementation and adoption of new products. The category comprises review articles, case studies, frameworks, and guides for entrepreneurs to bring their ideas to the market. (40 publications, 19%).

3.10 Evaluation (T10)

This theme focuses on evaluating digital health innovations and includes articles and reviews focusing on health technology assessment and the clinical effectiveness of digital health startups. (13 publications, 6%).

3.11 Conceptual framework of digital health entrepreneurship (T11)

The identified themes were sorted into a conceptual framework with the digital health venture as the central element shown in Fig. 8. This framework provides an overview of digital health entrepreneurship based on the literature. Digital health ventures typically progress through a multistage strategy that commences with product and business development and culminates in implementation and evaluation. The

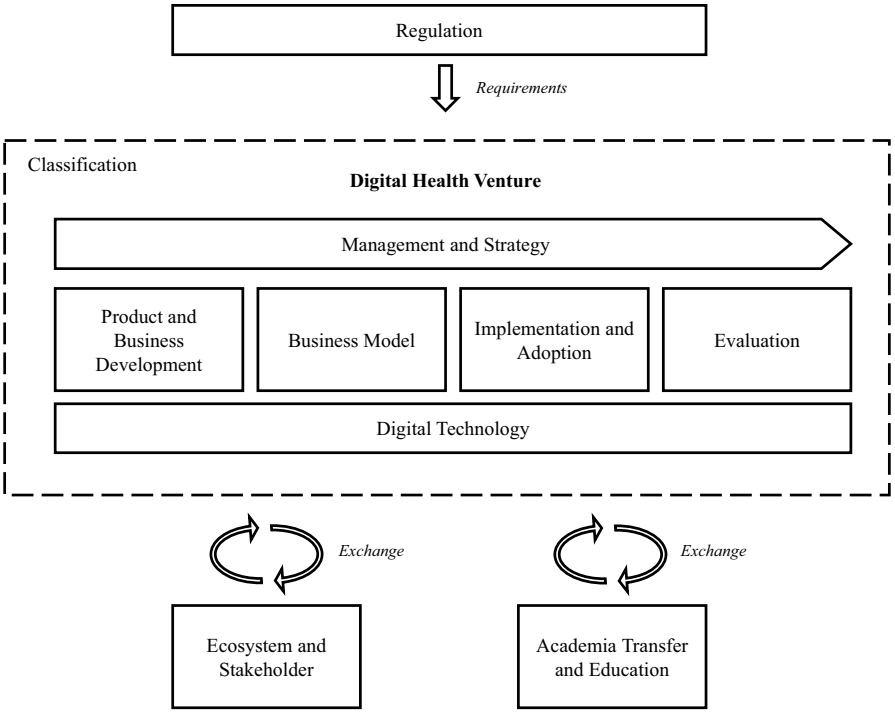

Fig. 8 A conceptual framework describing digital health entrepreneurship with internal and external building blocks based on the identified themes

startups rely on digital technology as the core of their products, while the business model is the heart that pumps life into the venture. The business model is built upon a compelling value proposition appealing to the interests of diverse healthcare stakeholders. Additionally, continuous engagement with stakeholders, academic partners, and the broader ecosystem provides valuable support to overcome barriers. Startups face regulatory requirements such as medical device regulations and data security laws. Evaluating the digital health product's benefits remains crucial for success.

4 Discussion

The following sections discuss the content and gaps of all identified themes in detail.

4.1 Academia transfer and education (T1)

Academia has played a crucial role in developing new medical and digital health products by turning research into practical solutions through spinoff companies (Letourneur et al. 2021; Mayrink et al. 2022; Merkel and Huth 2022). Nevertheless, several barriers impede the translation of research findings into clinical practice. However, research has focused on overcoming these barriers, and possible solutions have been described such as clinical partnerships, close collaboration with industry, funding, and entrepreneurial programs (Letourneur et al. 2021). In the realm of funding health innovations, a decision-support tool for academic medical centers has been developed and tested (Cai et al. 2023). Translational guidelines for startups have been developed based on the experiences of academic spinoffs (Moore et al. 2022). These case studies outline the challenges and steps in translating research into practical applications (Lehoux et al. 2014; Lopez et al. 2019).

Education plays a vital role in turning research into practical solutions. Several educational programs offered by universities and incubators aim to promote entrepreneurship in the medical device industry (Ribeiro et al. 2019; Suryavanshi et al. 2020). For instance, the Stanford Biodesign Program, established in 2001, helps multidisciplinary teams to identify clinical needs and develop a business strategy (Brinton et al. 2013). It has recently been applied to digital health (Robinson 2021). Another course focuses on teaching digital health entrepreneurship as a discipline (Greven et al. 2020). Although these are some positive examples, digital health education does not usually include entrepreneurial elements. Especially medical school curricula frequently appear to be outdated in teaching about new digital technologies in healthcare (De Oliveira et al. 2023).

To facilitate the creation of successful medical technology ventures in the future, entrepreneurial education should be incorporated into the curricula of medical engineers, physicians, and other relevant stakeholders (Manbachi et al. 2018; Friebe 2020; Wulfovich 2020; Fritzsche et al. 2021). Initial results from a summer school have demonstrated that interdisciplinary work between medicine, engineering, and computer science can motivate students and enhance their knowledge of digital health innovations (Martens et al. 2023). Little research focuses on entrepreneurial digital health education and the specific content that should be taught.

4.2 Ecosystem and stakeholder (T2)

In classical entrepreneurship, some startup stakeholders are customers, investors, and partners. For digital health startups, this stakeholder landscape can become significantly more complex. Stakeholders are typically patients, healthcare providers, governments, and insurance companies (Nilsen et al. 2020). Research has shown that it is essential for health startups to engage with stakeholders early in the development process (Barlow et al. 2006; Nilsen et al. 2020), as failing to do so can lead to conflicting perspectives and interests (Lyles et al. 2021). Early stakeholder analysis is an effective strategy for engaging stakeholders (Lee and Sheikh 2016). Another way to facilitate engagement is through living labs, which provide a more advanced platform for early stakeholder involvement (Bygholm and Kanstrup 2017; Swinkels et al. 2018). Scholars have developed guidelines on how to establish such living labs, drawing on practical insights (Fotis et al. 2023).

Alliances between startups and other organizations are essential for the success of digital health products (Kikuchi et al. 2021; Capponi and Corrocher 2022). Even failed relationships can provide valuable learning experiences (Hasche and Linton 2018). Particular academia-industry alliances contribute to later success (Ford et al. 2019, 2021). Funding a digital health venture can be challenging. Academia-industry partnerships might be a basis for receiving grants or support through technology transfer programs (Ford et al. 2021).

Another research path looks at entrepreneurial and innovation ecosystems and has built guidelines or models for implementing digital health ecosystems in which startups can thrive (Hermes et al. 2020). These systems involve interactions between startups and various institutions, including government agencies and independent organizations (Loebker et al. 2021; Bhattacharyya et al. 2022). Digital health accelerator programs are among the ecosystem actors, capable of supporting startups. However, a significant challenge is the lack of research evidence for the products, an area where accelerators currently do not provide sufficient support (Njoku et al. 2023).

Further research could examine how startups shape their ecosystems and their roles within them (Denoo and Yli-Renko 2019). While some preliminary research on the roles of startups in the ecosystem exists (Mohammadparast Tabas et al. 2023), further research could focus on the evolving roles in digital health. Additionally, there is a need for practical strategies for managing alliance partners, which is a crucial factor for the success of digital health startups (Denoo and Yli-Renko 2019). More concepts on how to practically support digital health startups, particularly in areas like evidence generation, should be developed.

4.3 Product and business development (T3)

Medical device development is often guided by roadmaps, such as the stage-gate process, which defines various quality gates throughout the product life cycle (Pietzsch et al. 2009), or the Biodesign process developed at Stanford (Balamurugan and Naveen 2021). These frameworks provide a structured approach to the product or

startup life cycle. Recently, there has been a shift towards methods that guide entrepreneurs in designing digital health solutions. This marks the transition from classical product development as conducted in hardware-heavy medical technology companies (waterfall method) towards agile methods needed to develop digital solutions. One of the most cited methods developed for digital health is the Centre for eHealth Research Roadmap (CeHRes roadmap) (van Gemert-Pijnen et al. 2011). Other state-of-the-art methods often incorporate lean (Eppley et al. 2021), design thinking (Eckman et al. 2016; Mummah et al. 2016; Chokshi and Mann 2018), human-centered design (Levander et al. 2023), design science research (Gregório et al. 2021) or the lifecycle itself (Bhavnani et al. 2017) to further involve stakeholders in the development process. Much of the literature discusses patient-centered approaches and value cocreation that might serve as the basis for patient empowerment through digital technologies and safe products (Kraus et al. 2021; Rassi-Cruz et al. 2022). A recent study attempted to incorporate requirements related to risk management into the co-design process (Sternini et al. 2023). Future research might build upon these findings to create co-design methods for regulated digital health products. Some research suggests that a more holistic approach, which considers both human-centered design and environmental sustainability, may be necessary to develop digital health products (van Velsen et al. 2022). There is limited literature on methods for developing solutions for specific user groups, such as older adults, who face unique challenges (Matthew-Maich et al. 2016).

Various toolkits and methods have been created to assist with the practical application of these methods, providing more detailed instructions for the different design phases of digital health products (Hughes et al. 2021; Kayser et al. 2022; Kip et al. 2022; Marvel et al. 2018). Another emerging approach is focusing on responsibility during the early stages of business development (Oftedal et al. 2019; Naughton et al. 2023, Thapa and Iakovleva 2023). While the literature on these methods is extensive, few case studies demonstrate their practical application or incorporate startup specifics.

4.4 Business model (T4)

Creating a viable business model is the key element of entrepreneurship (Wulfovich 2020), and it also seems crucial for digital health entrepreneurship (Limburg et al. 2011). A digital health business model might involve a significant redesign compared to traditional or medical device business models (Steinberg et al. 2015). With their flexible structure, startups are particularly well-suited to make this shift (Herrmann et al. 2018). Tariq (2023) states that six forces impact business model innovation: funding, accountability, industry players, technology, public policy, and customer. Recent literature reviews have identified various business models developed for DHTs and concluded a lack of evaluation regarding their usefulness (Kelley et al. 2020; Velayati et al. 2022). Key components of digital health business models are the value proposition, key processes, profit formula, and critical resources (Sterling and LeRouge 2019; Velayati et al. 2021). The CompBizMod framework for complex healthcare services is one example of the few business models validated by

experts (Peters et al. 2015). Another example tries to include sustainability aspects in the business model (Oderanti et al. 2021). Some studies describe digital health business modeling based on use cases (Kijl and Nieuwenhuis 2011; Sprenger 2016; Alnahdi 2023). Sprenger (2016) investigated the utility of a pattern-based business model design. Alnahdi (2023) applied Osterwalder's Business Model Canvas and Value Proposition Canvas to the domain of digital health, suggesting innovative approaches for structuring and articulating the value of digital health initiatives.

Reimbursement through health insurances is one strategy to achieve a sustainable revenue model in healthcare (Herberz et al. 2018). Nevertheless, the path to reimbursement can be tedious and involves engaging healthcare insurers and complying with regulations (Herberz et al. 2018). Governments worldwide are passing new laws to encourage startups and create new reimbursement pathways. Van Kessel et al. (2023) analyzed the digital health reimbursement landscape in nine countries, finding that diversity among these systems creates barriers for entrepreneurs. An example of a reimbursement pathway is Germany's digital health application (DiGA) framework. Under this framework, digital health products that provide direct patient care must meet a complex set of regulations and demonstrate a positive impact on healthcare. Once they fulfill these requirements, physicians can prescribe these products, and all public German health insurances reimburse the costs (Loebker et al. 2021). Although these frameworks require improvements, they have demonstrated the potential to facilitate new, digital health-specific reimbursement pathways for startups (Schlieter et al. 2023).

Another element that is essential for digital health business models is the value proposition (Chen et al. 2013; Shaw et al. 2018; Lentferink et al. 2020). One study identified nine types of value propositions commonly used by digital health companies in the developing world (Gorski et al. 2016).

Apart from the value proposition, securing funding plays an important role in the early stages of a business model. Due to potential delays in market access caused by regulations and mandatory clinical evaluations in the digital health industry, digital health entrepreneurs must ensure their business model is well-supported by investments to overcome the challenging 'valley of death' (Manbachi et al. 2018). In addition, many conventional sources of capital are not familiar with healthcare (Tariq 2023). For this, it is essential to understand early-stage funding environments and to present a clear differentiation from competition (Wulfovich 2020).

Future research might explore business models of existing ventures (Chakraborty et al. 2021), describe business model design (van Meeuwen et al. 2015), and models that allow for effective value capture (Denoo and Yli-Renko 2019). It is crucial to address the specific digital health business model challenges that include the complex stakeholder landscape (Nilsen et al. 2020), the revenue model and reimbursement challenges startups face (Hagen and Lauer 2018; Chakraborty et al. 2023a), regulations (Berensmann and Gratzfeld 2018; Chakraborty et al. 2023a), and funding (Joseph et al. 2011). By understanding the various tools, key components, and business models in digital health, entrepreneurs can design and implement solutions that meet the needs of patients and healthcare providers. A preliminary study has explored digital platform business model changes over time (Essen et al. 2023). Digital platforms offer new avenues for value creation and emerging digital platform

business models in healthcare could be explored further (Lehoux et al. 2014; Konopik 2023).

4.5 Classification (T5)

Several studies have attempted to classify digital health startups based on various dimensions, such as customer need (Herrmann et al. 2018), strategy (Labrique et al. 2013), value proposition (Gorski et al. 2016), other elements of the business model (Steinberg et al. 2015; Peters et al. 2015; Denoo and Yli-Renko 2019), or innovation routes (Janssen et al. 2013). By differentiating between a consumer, a provider, an insurer, and a government route, Janssen et al. (2013) describe four ways digital health startups can handle market access. Some studies in theme five have focused on specific regions, such as North America (Steinberg et al. 2015), Europe, or developing countries (Gorski et al. 2016), while others have taken a more global approach. Gehde et al. (2022) sorted German digital health startups based on their area of activity and digital technologies used and identified five overarching configurations. However, current research has not yet provided a comprehensive, holistic classification of startups, which could help describe, evaluate (Botha et al. 2018), and guide (Janssen et al. 2013) new ventures. Future research could address this gap by developing a comprehensive description and classification of digital health startups.

4.6 Management and strategy (T6)

While this theme is related to the business model, it focuses on entrepreneurial and strategic management guidelines needed to build successful digital health startups. Norris et al. (2009) developed a sustainable mobile health strategy framework consisting of three phases: identifying applications, channeling development activities, and confirming activities. Other frameworks summarize best practices for creating and managing digital health innovations (Urueña et al. 2016; Muhos et al. 2019; Barbazzeni et al. 2022; Schee Genannt Halfmann et al. 2022; Biancone et al. 2023). Boonstra et al. (2011) focus on designing and managing digital health innovations by addressing the value chain, value shop, and value network theories, which have connections to the business model. It appears that the frameworks are often not practically applied. This is supported by recent research that concludes that startups often lack a strategic guide for successful market access and reimbursement (Hagen and Lauer 2018).

Furthermore, research has been conducted on the entrepreneurial capabilities needed in the digital health sector, including digital technology knowledge, strategic abilities, and business model capabilities. Challenges entrepreneurs face are network management (Muhos et al. 2019) and the management of sensitive patient information (Gauthier et al. 2018). Other elements for successful digital health innovation projects include the implementation of rigorous evaluation methods and the cultivation of organizational agility (Urueña et al. 2016). Future research could use quantitative methods in digital health management (Angerer et al. 2022) or investigate the

strategic approach of skating the line between a wellness product and a regulated device (Simon et al. 2022). By understanding the management decisions and strategies that have been successful in the digital health space, researchers and practitioners can gain valuable insights into the effective management and growth of their digital health ventures.

4.7 Regulation (T7)

Regulations such as the medical device regulation (MDR) and the in vitro diagnostic medical device regulation (IVDR) in Europe aim to ensure the safety of medical devices. Nevertheless, they can pose challenges for small companies seeking to bring their products to market (Baines et al. 2022). Only certain types of digital health products fall under medical regulations. In Europe, primarily products intended to diagnose, detect, prevent, monitor, treat, or alleviate a disease or disability are subject to the MDR and are categorized into risk classes according to their potential impact on patients (Berensmann and Gratzfeld 2018). Subsequently, a robust quality management system and technical documentation must be established to guide and document product development. Furthermore, the safety and effectiveness of a digital health innovation must be demonstrated through a clinical evaluation (Berensmann and Gratzfeld 2018). These evaluations may include clinical trials which present a significant challenge due to the risk of potential failure (Olivier et al. 2021). Overall, numerous legal requirements govern the entry of a regulated product into the market, and the product can only enter the market once it undergoes a final conformity assessment (Berensmann and Gratzfeld 2018). Entrepreneurs must be aware of this regulatory environment.

Scholars have attempted to clarify whether regulations apply to a digital health product by creating simplified decision trees (Lukas et al. 2021; Seifert et al. 2022). Garell et al. (2016) proposed a legal framework to support entrepreneurs navigating regulatory challenges. Another framework focuses on providing guidance for the digital health application (DiGA) process in Germany (Ataiy et al. 2023). Furthermore, suggestions have been made to incorporate regulatory information into university education, provide better tools and resources, and create standardized templates of regulatory documents (Baines et al. 2022). Case studies of startups, as conducted by Herberz et al. (2018), that have successfully navigated the certification process may help others achieve compliance (Baines et al. 2022). A further study proposes different combinations of DHTs and offers regulatory perspectives on each case (Colloud et al. 2023). Kheir et al. (2021) interviewed entrepreneurs and outlined the structure of a quality management system implemented by a medical startup. By adapting the intended use of a product, a startup can control whether a product falls into the lifestyle and wellness product category (not targeting a specific medical condition and therefore not subject to regulation) or whether it is a regulated device (intended to treat a particular medical condition and subject to regulatory oversight). Simon et al. (2022) describe this as the possibility of skating the line between the two worlds and give first guidance for companies on benefits and associated risks. Another study proposes that the United Kingdom may become a highly

attractive location for initially developing digital health solutions, as UK regulators select innovative and well-designed regulatory features (Gilbert et al. 2023).

Digital health products require strong data security and privacy measures as part of the regulations and to ensure user acceptance (Wilkowska and Ziefle 2012). In Europe, the general data protection regulation (GDPR) sets requirements for protecting personal data (Frielitz et al. 2019), and the MDR sets further conditions. Current solutions for ensuring security and privacy in digital health products are insufficient (Wicks and Chiauzzi 2015). To ensure compliance with regulations and user needs, startups must develop a data security concept early on (Frielitz et al. 2019). Li et al. (2023) provide initial insights into the experience of health startups with cybersecurity. Still, little research focuses on how startups should handle data security privacy and which tools or certificates are recommended to fulfill regulatory and user requirements. While data protection is essential for medical products, wellness, and fitness apps may be subject to less regulation. Future research could explore business models that prioritize data protection while generating revenue for the company (Denoo and Yli-Renko 2019).

Although several contributions exist, regulatory paths are often unclear or have not been defined yet (Rassi-Cruz et al. 2022), and more research is needed to understand how startups can cope with the challenges.

4.8 Digital technology (T8)

Digital health products rely on various digital technologies to function, with artificial intelligence (AI) being one of the most important (Wulfovich 2020).

AI has many potential uses in healthcare, including decision support, image analysis, and chatbots (Arora 2020). However, there are numerous challenges to adopting AI in healthcare (Singh et al. 2020), which is why practical frameworks have been developed to provide guidance on best practices for founders (Arora 2020; Higgins and Madai 2020). One of the frameworks consists of a regulatory, clinical, data, and machine-learning model strategy (Arora 2020). Large amounts of data are becoming increasingly available through electronic patient records and real-time patient data (Arora 2020) from wearable devices, which entrepreneurs should consider when developing digital health products (Dinh-Le et al. 2019). Closely related to the AI applications, promising uses of virtual reality, augmented reality and mixed reality in digital health are personalized occupational, educational, and home healthcare applications (Kim et al. 2023).

Another technology with potential healthcare applications is blockchain, a distributed ledger technology with decentralized principles that could improve accessibility and security in healthcare. Opportunities lie in improved patient record management (Badri et al. 2023), clinical trial trustworthiness, and protection of telehealth systems (Yaqoob et al. 2022). However, practical blockchain applications in healthcare are currently limited (Chen et al. 2019). In a first study, Russo-Spena et al. (2023) identified three impacts of blockchain for

value co-creation in healthcare: improving service interaction, impacting actors' engagement, and fostering ecosystem transparency.

To increase their chances of success, entrepreneurs in the digital health field should have strong technological skills and be aware of the need for a large amount of data for AI applications (Wulfovich 2020).

4.9 Implementation and adoption (T9)

Although the COVID-19 pandemic has favored the implementation of digital health tools (Golinelli et al. 2020), they may not be adopted due to system-imposed (Hobeck et al. 2021), technological and organizational barriers (Renukappa et al. 2022). Some examples are a lack of information technology infrastructure, the impact of regulatory pressures (Lim and Anderson 2016), and resistance to change (Scott Kruse et al. 2018; Van Velthoven and Cordon 2019). Further research is needed to assess the efficacy of financial incentives to promote adoption, as the current evidence is limited (Zanaboni and Wootton 2012).

There is a significant amount of literature on effectively implementing and adopting digital health solutions. Various frameworks have been developed to aid in their successful implementation (MacFarlane et al. 2011; Joseph et al. 2011; van Dyk 2014; Ross et al. 2016; L'Engle et al. 2017; Lundin and Dumont 2017; Greenhalgh et al. 2017; Hobeck et al. 2021; Quanbeck et al. 2021; Verweij et al. 2022; Talwar et al. 2023). One example is a framework to push health app prescriptions by physicians (Gordon et al. 2020), while another focuses on the consumer and user role in adopting digital solutions (Talwar et al. 2023). Nevertheless, there is no one-size-fits-all approach, and it is recommended to take a multidisciplinary approach (Hochmuth et al. 2020). There is a lack of research on organizational issues related to digital health adoption (Cresswell and Sheikh 2013). Some initial work on barriers and enablers for adoption has been published recently (Zhao et al. 2023; Olaye et al. 2023).

Success factors for the adoption and market entry of medical startups have been identified as similar to general startup success factors (Lee et al. 2019). Nevertheless, specific to digital health are access to distribution channels, financing, health insurance cooperation, partnerships (Hanneken 2018; Lux and Kempf 2021), a robust technological infrastructure, revenue generation ability (Chakraborty et al. 2023b), and early attention to regulations (Bengtson et al. 2022). Some research focuses on the decision-maker perspective for success factors (Prodan et al. 2022). From the customer's perspective, quality, personalization, and data risk are the main predictors of DHT adoption (Saheb 2020). Healthcare staff may hesitate to risk potential changes to valued existing services (Sanders et al. 2012). A perceived positive impact on the interaction between healthcare staff is another success factor (Murray et al. 2011). Only a few authors mention scale-up as part of adopting digital health ventures (Greenhalgh et al. 2017; L'Engle et al. 2017; Proctor et al. 2021), although scale-up is a significant challenge.

4.10 Evaluation (T10)

Digital health evaluation involves health technology assessment (HTA) from an entrepreneurial perspective and the evaluation of digital health startup characteristics.

The origin of HTA lies in evidence-based healthcare. It advises decision-makers on the potential impact of introducing new health technologies (Wang et al. 2021) for establishing high-quality health systems (Ming et al. 2022). The areas of focus in HTA for digital health include evaluation of safety, clinical effectiveness, usability, economic aspects, and interoperability (Kolasa and Kozinski 2020). Using HTA tools early in product and business development can be helpful for entrepreneurs (Wang et al. 2021). Some approaches promise the rapid assessment of health technologies (Cai et al. 2023) or dynamic HTAs with real-world evidence (Brönneke et al. 2023). More evidence is needed for future sustainability evaluations of digital health (Degavre et al. 2022).

Within this theme, one research stream evaluates different characteristics of digital health startups. A study on SaMD companies in the United States found that incumbents predominate, while startups seem to contribute more disruptive innovations. The study concludes that disruptive innovations in the field are only possible with access to sufficiently large data sets (Yu et al. 2023). One study proposed a tool to assess the responsibility of digital health solutions (Lehoux et al. 2023). Another study measured the clinical validity of digital health startups and found evidence for a low level of clinical robustness (Day et al. 2022). A separate investigation concurred with these results, highlighting that various healthcare unicorns lack scientific evidence (Cristea et al. 2019). It may be advisable for healthcare startups to invest in clinical validation efforts to increase trust in their products, as relying solely on internal data may not be sufficient to establish their validity (Cristea et al. 2019). Nevertheless, clinical trials might fail (Olivier et al. 2021), which imposes new risks.

5 Conclusion

With the goal of this work to map the scientific evidence of digital health entrepreneurship, a systematic literature review combining digital health and entrepreneurship was conducted to understand the current state of research in this area. After reviewing 6993 papers from multidisciplinary databases, 164 articles related to digital health entrepreneurship were identified.

Health and medicine journals, along with digital health-specific journals, were found to be the primary sources of publications. Additionally, mainly business and a few engineering journals revealed relevant publications. These results show that the digital health entrepreneurship literature is based on the interplay of different disciplines as it is a combination of ‘digital’, which is driven by engineering and computer science disciplines, ‘health’, which is part of medical studies, and ‘entrepreneurship’, belonging to management sciences. This observation leads to the question, of why digital health entrepreneurship literature is not only published through

classical entrepreneurship journals. An explanation might be that the primary audience for health innovations includes healthcare professionals and health researchers, who tend to refer to digital health and medicine journals. Additionally, business journals may exhibit specific methodological preferences that do not always align with the interdisciplinary nature prevalent in digital health entrepreneurship studies. Lastly, while entrepreneurship as a discipline is well-established, digital health entrepreneurship is still emerging. As a result, business journals are gradually adapting to include more studies related to this area.

While empirical and conceptual research methodologies are balanced for the examined dataset, qualitative methods dominate over quantitative methods. Although qualitative methods have their advantages, the digital health entrepreneurship literature could benefit from more quantitative work. (RQ1).

Through an iterative and inductive research process, we derived ten themes relevant to digital health entrepreneurship: Academia Transfer and Education (T1), Ecosystem and Stakeholder (T2), Product and Business Development (T3), Business Model (T4), Classification (T5), Management and Strategy (T6), Regulation (T7), Digital Technology (T8), Implementation and Adoption (T9), and Evaluation (T10). These themes were then organized into a conceptual framework depicting the internal and external building blocks of digital health entrepreneurship.

It became clear that the content of these themes was particular to digital health entrepreneurship. The requirements of medical device regulations and data security laws are unique to digital health ventures. Additionally, the acceptance of the technology plays an important role. Another crucial element is the exchange with the ecosystem, stakeholders, and academia, as digital health startups often need to survive clinical evaluations before entering the market successfully. Strong partnerships are required due to costly certifications and to overcome the valley of death.

The analysis of the research themes showed an unequal distribution of scientific evidence. The theme with the most robust body of evidence was Implementation and Adoption. In contrast, the themes with the least evidence were Classification, Evaluation, and Digital Technology. The remaining themes had a moderate level of evidence. (RQ2).

The proliferation of digital technologies, such as smartphones, artificial intelligence, and distributed ledger technology, has opened up opportunities for digital health entrepreneurs. Further research is needed to understand how to effectively create and utilize these opportunities, particularly in the case of distributed ledger technology, which has significant potential but many unresolved questions. While early evidence suggests that there are various approaches to structuring the digital health industry, they are not always based on real-world data. Tools and methods such as human-centered design and lean startup have been proposed for digital health ventures, but there is limited empirical evidence of their effectiveness. The business model, a central aspect of any entrepreneurial activity, has received increasing attention in digital health research. Primary research indicates how to develop a business model in digital health. Still, there is no consensus about which models to use, and they often have little practical use. The revenue model and possible reimbursement pathways have seen little attention. Descriptions of digital health venture strategies, such as skating the line between wellness products and medical devices,

Table 4 Key challenges in digital health entrepreneurship based on the ten identified themes

Theme	Future research agenda
Academia transfer and education	• Which success factors can be identified for digital health academia transfer? • How can digital health entrepreneurship be taught as a discipline in universities?
Ecosystem and stakeholder	• How can accelerators best support digital health startups especially in demonstrating clinical evidence? • How can business partnerships contribute to the success of digital health startups?
Product and business development	• How valuable are entrepreneurial design methods in practice? • How can medical device regulations be incorporated into product and business development? • How can customers with special needs be best addressed by entrepreneurial design methods?
Business model	• How can a business model be best adapted to the complex healthcare stakeholder network? • Which reimbursement pathways exist and when should they be used? • How to design value propositions to address multiple stakeholders? • What implications do medical device regulations have for the business model? • How can funding help digital health startups to overcome the valley of death? • Which types of business model innovation emerge from DHT?
Classification	• Which types of startups emerge in the digital health field and how can they be systematically described?
Management and strategy	• How to apply digital health strategy guides in practice?
Regulation	• Which regulatory requirements exist for digital health startups? • How and why do digital health startups skate the line between regulated and wellness/lifestyle products? • How can entrepreneurs be supported in developing a regulatory strategy? • How can entrepreneurs have access to open regulatory knowledge?
Digital technology	• Which business opportunities in healthcare exist for emerging digital technologies like blockchain technology?
Implementation and adoption	• How can digital health ventures be scaled up successfully? • What are the key factors for the acceptance of DHT by users?
Evaluation	• How can health technology assessment be incorporated early into the venture building? • How can digital health startups improve their clinical robustness?

exist, but startups often still miss applicable guidelines. While the implementation, adoption, and evaluation of digital health solutions have been studied on a larger scale, there is still a need for research on the clinical robustness of digital health startups and the incorporation of health technology assessment early in the business formation process.

Digital health entrepreneurs often operate in a highly regulated industry where various stakeholders must be satisfied. The literature highlights the importance of

partnerships and a sustainable ecosystem for the success of startups in this field. While the ecosystem has been described successfully in the literature, guidance on partnerships has been difficult due to the diversity of individual stakeholder dynamics. Academia is a vital stakeholder and crucial in translating ideas and research into practice, particularly in this complex environment. While some programs currently exist that combine entrepreneurship education and digital health, further research could examine how entrepreneurial digital health courses should be designed.

The specific regulatory requirements for startups in this field have been relatively understudied, with limited guidance on compliance and medical device classifications. Access to regulatory knowledge, often only available through expensive consulting services, could greatly benefit entrepreneurs. Developing practical guidelines for data security is essential for user acceptance and adoption. To summarize these findings, key challenges are presented in Table 4. (RQ3).

In conclusion, the literature review on digital health entrepreneurship has revealed a rapidly growing field with significant potential. The historical roots of the area cause heterogeneity among the definitions of digital health, and researchers need to be aware of these discrepancies. In contrast to the clear themes identified in this work, the citation map based on the data set showed one central cluster and sparse connections between the remaining articles. This might indicate that the research remains dynamic, with researchers encountering challenges in finding and building upon the work of their peers. A possible reason for this could be the heterogeneity of terminology used surrounding digital health and the fact that multiple disciplines publish in their journals, making it difficult for researchers to build upon the work of others. We identified several areas where more research is required, including a structured description of the industry and its business models, strategic evidence for startups, and the role of regulatory environments. Still, our findings suggest that digital health entrepreneurship has the potential to revolutionize healthcare delivery and improve patient outcomes. More research is needed to make this vision a reality.

5.1 Theoretical contribution

Previous reviews of digital health entrepreneurship and digital health startups have been published (Chakraborty et al. 2021, 2023a; Sreenivasan and Suresh 2022). Nevertheless, they have only covered a limited number of sources or have only focused on digital health startups themselves. As a result, important aspects have been overlooked. Therefore, this study has two main significant theoretical contributions.

Primarily, a holistic definition of digital health entrepreneurship was given, incorporating digital health terms that have evolved over time. With this definition, a literature review integrating multidisciplinary databases resulted in a large volume of relevant literature and a comprehensive overview of the field. Through this review, we show that digital health entrepreneurship is compromised out of contributions from medical, business, and engineering disciplines.

Furthermore, this study is the first to develop a comprehensive theoretical framework for digital health entrepreneurship. Based on a literature review and ten inductively developed digital health entrepreneurship themes, this framework represents

the first of its kind. The main advantages of this framework lie in its simplicity and comprehensive approach to describing digital health entrepreneurship, reaching beyond the digital health venture itself.

5.2 Practical contribution

This review can serve as a valuable guide for researchers seeking to contribute to the literature on digital health entrepreneurship, assisting them in identifying an appropriate research outlet and literature gaps. In this way, the work may catalyze future more practice-oriented research. Furthermore, the identified research challenges might pave the way for future research.

Entrepreneurs benefit from understanding whether they operate within the digital health field or within the traditional medical technology field, as these areas are significantly different. This review establishes clear terminology and a framework to support this distinction and presents entrepreneurial tools and knowledge for practical application in digital health. In this context, the literature review provides essential guidance for digital health entrepreneurs at various venture stages. Early-stage digital health ventures can take advantage of the product and business development tools outlined. Concerning the core of entrepreneurship, which involves building a successful business model, the review introduces business model tools and examples for developing a business model in the digital health domain. Moreover, it highlights the importance of early navigation through regulatory landscapes and details regulatory decision support tools that could assist in compliance efforts. The review also emphasizes the significance of stakeholder engagement and collaboration with academia, offering strategies for effective interaction. For later venture stages, it summarizes guidelines for successful implementation and scaling up of DHT. By integrating these insights, entrepreneurs can navigate the complexities of digital health entrepreneurship effectively, paving the way for innovation and sustainable success.

5.3 Limitations

We had to deal with significant literature through the search strategy applied. One limitation of the study might be that some relevant literature was missed based on the search method used and the inclusion and exclusion criteria defined. In addition, no grey literature was included in the review that might contain additional contributions to the field. Based on the review results, further work might be needed to give entrepreneurs practical tools and knowledge to leverage their business ideas.

Appendix A: Concept matrix with all the research themes

see Table 5.

Table 5 Concept matrix

Publication	Classification	Academia transfer	Management and strategy	Business and product development	Business model	Implementation and adoption	Ecosystem and stakeholder	Regulation	Digital technology	Evaluation
Ahmed et al. (2019)						×	×	×	×	×
Alnahdi (2023)					×					
Angerer et al. (2022)			×							
Arora (2020)									×	
Ataiy et al. (2023)				×				×		
Badri et al. (2023)									×	
Baierl et al. (2019)	×				×		×	×		
Baines et al. (2022)								×		
Balamurugan and Naveen (2021)				×						
Barbazzeni et al. (2022)			×							
Barlow et al. (2006)							×			
Bengtson et al. (2022)						×				
Berensmann and Gratzfeld (2018)								×		
Bhattacharyya et al. (2022)							×			
Bhavnani et al. (2017)				×			×			
Biancone et al. (2023)			×			×				
Boonstra et al. (2011)			×							
Botha et al. (2018)	×									
Bratan et al. (2022)	×				×		×	×		
Brinton et al. (2013)		×								
Brönneke et al. (2023)										×

Table 5 (continued)

Publication	Classification	Academia transfer	Management and strategy	Business and product development	Business model	Implementation and adoption	Ecosystem and stakeholder	Regulation	Digital technology	Evaluation
Bygholm and Kanstrup (2017)							×			
Cai et al. (2023)		×								×
Capponi and Corrocher (2022)							×			
Chakraborty et al. (2021)					×	×	×	×	×	
Chakraborty et al. (2023a)										
Chakraborty et al. (2023b)						×				
Chen et al. (2013)					×					
Chokshi and Mann (2018)				×						
Colloud et al. (2023)								×		
Cresswell and Sheikh (2013)						×				
Cristea et al. (2019)										×
Day et al. (2022)										×
Degavre et al. (2022)										×
De Oliveira et al. (2023)		×								
Dinh-Le et al. (2019)									×	
Eckman et al (2016)				×						

Table 5 (continued)

Publication	Classification	Academia transfer	Management and strategy	Business and product development	Business model	Implementation and adoption	Ecosystem and stakeholder	Regulation	Digital technology	Evaluation
Ehn et al. (2021)				×						
Eppley et al. (2021)				×						
Essen et al. (2023)					×					
Ford et al. (2019)							×			
Ford et al. (2021)							×			
Fotis et al. (2023)							×			
Friebe (2020)		×								
Frielitz et al. (2019)								×		
Fritzsche et al. (2021)		×								
Garell et al. (2016)								×		
Gauthier et al. (2018)			×							
Gehde et al. (2022)	×				×					
Gentili et al. (2022)										×
Gilbert et al. (2023)								×		
Golinelli et al. (2020)						×				
Gordon et al. (2020)						×				
Gorski et al. (2016)	×				×					
Greenhalgh et al. (2017)						×				
Gregório et al. (2021)				×						
Greven et al. (2020)		×								
Gutiérrez-Ibarluzea et al. (2017)				×						

Table 5 (continued)

Publication	Classification	Academia transfer	Management and strategy	Business and product development	Business model	Implementation and adoption	Ecosystem and stakeholder	Regulation	Digital technology	Evaluation
Hagen and Lauer (2018)			×					×		
Hasche and Linton (2018)							×			
Herberz et al. (2018)			×			×				
Hermes et al. (2020)					×		×			
Herrmann et al. (2018)	×				×					
Higgins and Madai (2020)				×					×	
Hobeck et al. (2021)						×				
Hochmuth et al. (2020)						×				
Hughes et al (2021)				×		×				
Janssen et al. (2013)	×		×							
Joseph et al. (2011)						×				
Kayser et al. (2022)				×						
Kelley et al. (2020)					×	×				×
Kheir et al. (2021)								×		
Kijl and Nieuwenhuis (2011)					×					
Kikuchi et al. (2021)							×			
Kim et al. (2023)									×	
Kip et al. (2022)				×						
Kolasa and Kozinski (2020)										×

Table 5 (continued)

Publication	Classification	Academia transfer	Management and strategy	Business and product development	Business model	Implementation and adoption	Ecosystem and stakeholder	Regulation	Digital technology	Evaluation
Konopik (2023)					×					
Kraus et al. (2021)			×	×						
Thapa and Iakovleva (2023)				×						
Labrique et al. (2013)	×									
Lee and Sheikh (2016)							×			
Lee et al. (2019)						×				
Lehoux et al. (2014)		×			×					
Lehoux et al. (2023)										×
L'Engle et al. (2017)						×				
Lentferink et al. (2020)					×					
Letourneur et al. (2021)		×								
Levander et al. (2023)				×						
Li et al. (2023)								×		
Lim and Anderson (2016)						×				
Loebker et al. (2021)							×			
Lopez et al. (2019)		×								
Lukas et al. (2021)								×		
Lundin and Dumont (2017)						×				
Lux and Kempf (2021)						×				
Lyles et al. (2021)							×			

Table 5 (continued)

Publication	Classification	Academia transfer	Management and strategy	Business and product development	Business model	Implementation and adoption	Ecosystem and stakeholder	Regulation	Digital technology	Evaluation
MacFarlane et al. (2011)						×				
Matthew-Maich et al. (2016)				×		×				
Mair et al. (2012)						×				
Manbachi et al. (2018)		×								
Martens et al. (2023)		×								
Marvel et al (2018)				×						
Mayrink et al. (2022)		×								
Merkel and Huth (2022)										
Ming et al. (2022)										×
Mohammadparast Tabas et al. (2023)							×			
Moore et al. (2022)		×								
Muhos et al. (2019)			×							
Mummah et al. (2016)				×						
Murray et al. (2011)						×				
Naughton et al. (2023)				×						
Nilsen et al. (2020)							×			
Njoku et al. (2023)						×	×			
Norris et al. (2009)			×							
Oderanti et al. (2021)					×					
Oftedal et al. (2019)			×							

Table 5 (continued)

Publication	Classification	Academia transfer	Management and strategy	Business and product development	Business model	Implementation and adoption	Ecosystem and stakeholder	Regulation	Digital technology	Evaluation
Olaye et al. (2023)						×				
Olivier et al. (2021)								×		
Peters et al. (2015)	×				×					
Pietzsch et al. (2009)				×						
Prodan et al. (2022)			×			×				
Rassi-Cruz et al. (2022)								×		
Renukappa et al. (2022)			×			×				
Ribeiro et al. (2019)		×					×			
Robinson (2021)		×		×						
Ross et al. (2016)						×				
Russo-Spena et al. (2023)									×	
Saheb (2020)						×				
Sanders et al. (2012)						×				
Schee Genannt Halfmann et al. (2022)			×							
Schlieter et al. (2023)					×			×		
Scott Kruse et al. (2018)						×				
Seifert et al. (2022)								×		
Simon et al. (2022)			×					×		
Singh et al. (2020)									×	

Table 5 (continued)

Publication	Classification	Academia transfer	Management and strategy	Business and product development	Business model	Implementation and adoption	Ecosystem and stakeholder	Regulation	Digital technology	Evaluation
Sprenger (2016)					×					
Sreenivasan and Suresh (2022)						×	×		×	
Steinberg et al. (2015)	×				×					
Sterling and Lerouge (2019)					×					
Sternini et al. (2023)				×						
Suryavanshi et al. (2020)		×								
Swinkels et al. (2018)							×			
Talwar et al. (2023)						×	×			
Tariq (2023)										
Urueña et al. (2016)			×							
van Dyk (2014)						×				
van Gemert-Pijnen et al. (2011)				×						
Van Kessel et al. (2023)					×			×		
van Limburg et al. (2011)					×					
van Meeuwen et al. (2015)					×					
van Velsen et al (2022)				×						

Table 5 (continued)

Publication	Classification	Academia transfer	Management and strategy	Business and product development	Business model	Implementation and adoption	Ecosystem and stakeholder	Regulation	Digital technology	Evaluation
Van Velthoven and Cordon (2019)						×				
Velayati et al. (2021)					×					
Velayati et al. (2022)					×					
Verweij et al. (2022)						×				
Wang et al. (2021)										×
Wicks and Chiauzzi (2015)								×		
Wilkowska and Ziefle (2012)						×		×		
Wulfovich (2020)		×			×		×	×	×	
Yaqoob et al. (2022)									×	
Yu et al. (2023)										×
Zanaboni and Wootton (2012)						×				
Zhao et al. (2023)						×				

Appendix B: Journal ranking

See Table 6.

Table 6 Journals ranked by number of publications

Journal Name	Discipline	Article Count
Journal of medical internet research	Digital Health	19
Federal health bulletin	General Health and Medicine	7
Frontiers in public health	General Health and Medicine	4
International journal of environmental research and public health	General Health and Medicine	4
JMIR mHealth and uHealth	Digital Health	4
BMC health services research	General Health and Medicine	3
BMC medical informatics and decision making	Digital Health	3
Implementation science	General Health and Medicine	3
International journal of medical informatics	Digital Health	3
Journal of business research	Business	3
Journal of telemedicine and telecare	Digital Health	3
Sustainability	Other	3
Technological forecasting and social change	Business	3
Technovation	Business	3
Current directions in biomedical engineering	Engineering	2
Frontiers in digital health	Digital Health	2
Frontiers in medicine	General Health and Medicine	2
Health informatics journal	Digital Health	2
International journal of technology assessment in health care	General Health and Medicine	2
Journal of commercial biotechnology	Business	2

Table 6 (continued)

Journal Name	Discipline	Article Count
Journal of medical engineering & technology	Engineering	2
Journal of responsible innovation	Business	2
Medical devices: evidence and research	Engineering	2
mHealth	Digital Health	2
NPJ digital medicine	Digital Health	2
Studies in health technology and informatics	Digital Health	2
A journal of integrative biology	Other	1
Advanced healthcare materials	General Health and Medicine	1
Advanced intelligent systems	Engineering	1
Advanced science	Engineering	1
Annals of biomedical engineering	Engineering	1
BMC medicine	General Health and Medicine	1
Bulletin of the world health organization	General Health and Medicine	1
Business research	Business	1
Cardiovascular digital health journal	Digital Health	1
Childhood Obesity	General Health and Medicine	1
Cost effectiveness and resource allocation	Business	1
Diabetology & metabolic syndrome	General Health and Medicine	1
Digital health	Digital Health	1
European journal of clinical investigation	General Health and Medicine	1
Frontiers in pharmacology	General Health and Medicine	1
Global health action	General Health and Medicine	1
Global health, science and practice	General Health and Medicine	1
Health and technology	General Health and Medicine	1

Table 6 (continued)

Journal Name	Discipline	Article Count
Health policy and technology	General Health and Medicine	1
Industrial marketing management	Business	1
Informatics	Engineering	1
International entrepreneurship and management journal	Business	1
International journal of entrepreneurial behaviour & research	Business	1
International journal of healthcare technology and management	Business	1
International journal of industrial engineering and operations management	Business	1
International journal of innovation management	Business	1
International journal of network management	Business	1
International journal on advances in life sciences	General Health and Medicine	1
JMIR cardio	General Health and Medicine	1
JMIR diabetes	General Health and Medicine	1
JMIR human factors	Other	1
JMIR medical informatics	Digital Health	1
JMIR public health and surveillance	General Health and Medicine	1
JMIR research protocols	Other	1
Journal of business venturing insights	Business	1
Journal of evaluation in clinical practice	General Health and Medicine	1
Journal of general internal medicine	General Health and Medicine	1
Journal of law and the biosciences	Other	1
Journal of management information systems	Business	1
Journal of medical devices	Engineering	1
Journal of re attach therapy and developmental diversities	Other	1
Journal of small business & entrepreneurship	Business	1

Table 6 (continued)

Journal Name	Discipline	Article Count
Journal of the American college of cardiology	General Health and Medicine	1
Medical science educator	General Health and Medicine	1
Nature biotechnology	General Health and Medicine	1
Neural computing and applications	Engineering	1
Participatory design & health information technology	Digital Health	1
Research in social & administrative pharmacy	Other	1
Small enterprise research	Business	1
Smart health	Digital Health	1
Social science & medicine	General Health and Medicine	1
Sociology of health & illness	General Health and Medicine	1
Strategic Change	Business	1
Telemedicine and e-health	Digital Health	1
The journal of strategic information systems	Business	1
Therapeutic innovation & regulatory science	Business	1
Translational vision & technology	Business	1

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Declarations

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